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PATENT

Attorney Docket No. 03260.002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Stewart D. LYMAN

Serial No.: 08/399,404 — Group Art Unit: 1806

Filed: March 6, 1995 — Examiner: P. Gambel

For: EXTRACORPOREAL CELL CULTURE AND TRANS-PLANTATION KITS

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

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Dated: February 23, 1998

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Attorney Docket No. 03260.0027

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Applicant hereby appeals from the decision of the Examiner dated January 22, 1997, finally rejecting claims 1-7, 9 and 10. The appealed claims are set forth in the attached Appendix. Submitted herewith is a Petition for Extension of Time for five months, up to and including February 21, 1998, and a check for the fees for this extension of time and the filing of this brief.

Real Party in Interest

The real party in interest is Immunex Corporation.

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Related Appeals and Interferences

There are no appeals or interferences known to Appellant, Appellant's legal representative, or assignee, that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

The application as originally filed contained fifteen claims. In the Office Action dated April 3, 1996 (Paper No. 4), the Examiner stated that all of these claims were rejected.[1] Claims 8 and 11-15 were cancelled, and claims 1, 4, 6, 7, 9 and 10 were amended, by Applicant's amendment filed October 8, 1996 (Paper No. 6). In the final Office Action, dated January 22, 1997 (Paper No. 7), the Examiner stated that all of the pending claims, 1-7, 9 and 10, were finally rejected under 35 U.S.C. § 103.[2]

Status of Amendments

No amendment was filed subsequent to the final Office Action, dated January 22, 1997.

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[1] Although the Examiner stated that all claims were rejected, no grounds were given for the rejection of claim 5.

[2] In the text of the Office Action, no grounds were given for the rejection of claims 2, 3 and 5. If the Examiner intended to reject these claims, then any arguments directed to controverting the rejection of claim 1 are also applicable to claims 2, 3 and 5, as each of these claims depends from claim 1.

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Summary of the Invention

The claimed invention is a kit for isolating and expanding selected populations of cells, and in particular, for performing extracorporeal stem cell culture and transplantation (ESCCAT). The claimed kit can be used, for example, to isolate and expand particular cell populations for introduction into a patient who is undergoing or who has undergone cytoreductive therapy. Cytoreductive therapies such as administration of ionizing radiation or chemical toxins, which are used to treat cancer, result in myelosuppression or damage to bone marrow cells. Bone marrow cells are the source of hematopoietic cells, which give rise to a variety of types of mature blood cells. While cytoreductive therapies are beneficial in eliminating cancerous cells, the accompanying myelosuppression can result in cytopenia, or blood cell deficits, that increase the risk of infection and bleeding disorders. See the specification at page 1, line 15 to page 3, line 2.

It is therefore desirable to replenish hematopoietic cells in patients concomitant with or subsequent to cytoreductive therapy. The claimed kit is advantageous in this regard, as it provides a means of selecting, isolating and expanding a population of cells. Specification at page 3, lines 5-15.

Using the kit, cells of a desired phenotype are selected and isolated from a mixture of human cells. The isolated cell population is then exposed to a composition containing the flt3-ligand and an additional growth factor. Specification at page 8, lines 24-30. The flt3-ligand promotes proliferation of certain populations of hematopoietic cells. Specification at page 4, line 35 to page 5, line 10. The additional growth factor

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can be GM-CSF, G-CSF, IL-1, IL-3, IL-6, TPO, EPO, SF or a GM-CSF/IL3 fusion protein. Specification at page 3, lines 7-15. The addition of the flt3-ligand and other growth factor results in expansion of the isolated population of cells. Specification at page 4, lines 14-21.

Claim 1, from which all other pending claims depend, is directed to a kit for isolating and expanding a selected population of cells. The kit contains means for selecting cells of a desired phenotype from a mixture of human cells; means for isolating the selected cells from the mixture; means for incubating the isolated cells; a composition containing flt3-ligand and a growth factor; and cellular growth medium. Support for this claim can be found at, e.g., page 3, lines 6-15 in the specification.

In claim 2, the isolated cells are human hematopoietic stem or progenitor cells, which become committed to differentiate along certain lineages, e..g., erythroid, megakaryocytic, granulocytic, monocytic or lymphocytic. Support for this claim can be found at, e.g., page 11, lines 30-34 in the specification. The kit of claim 3 has a container for containing the mixture of human cells. Support for claim 3 can be found at page 4, lines 14-15 in the specification. In claim 4, which depends from claim 2, the means for selecting the hematopoietic stem or progenitor cells is at least one of the flt3 receptor binding protein or a monoclonal antibody that binds to a cellular marker, either CD34 or Thy-1. Support for this claim can be found at page 8, line 37 to page 9, line 3 in the specification.

Claim 5 also depends from claim 2, and is directed to a kit in which the cell population is selected using an antimetabolite and either SF or flt3-ligand. Exposure to

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the antimetabolite induces cell death in dividing, lineage committed cells, but not in quiescent cells. The kit of claim 5 thus allows the elimination of more differentiated cell types and specific selection of quiescent cells. Support for claim 5 can be found at page 9, lines 21-28 in the specification.

Claims 6, 7, 9 and 10 are directed to kits in which specified growth factors are used to expand the isolated cells. In claim 6, the growth factor is a GM-CSF/IL-3 fusion protein; in claim 7, it is IL-1; in claim 9, it is GM-CSF; and in claim 10, it is IL-3. Support for these claims can be found at, e.g., page 4, lines 4-12 in the specification.

Issues

The sole issue on appeal is whether the claimed invention is unpatentable under 35 U.S.C. § 103 over the combination of Heimfeld et al. (WO 93/0826) in view of Lyman (Cell 1993) or Lyman et al. (EP 0627487A2), Stewart et al. (Blood, 1993) and Gillis et al. (U.S. Patent No. 5,199,942).

Grouping of Claims

Appellant believes all the claims to be patentable. Even if all of the other claims were not patentable, however, claim 5, if written as an independent claim, would be separately patentable.

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